

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES**Subpart A—General Provisions**

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Subpart B—Clinical Chemistry Test Systems

862.1020 Acid phosphatase (total or prostatic) test system.

862.1025 Adrenocorticotrophic hormone (ACTH) test system.

862.1030 Alanine amino transferase (ALT/SGPT) test system.

862.1035 Albumin test system.

862.1040 Aldolase test system.

862.1045 Aldosterone test system.

862.1050 Alkaline phosphatase or isoenzymes test system.

862.1055 Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.

862.1060 Delta-aminolevulinic acid test system.

862.1065 Ammonia test system.

862.1070 Amylase test system.

862.1075 Androstenedione test system.

862.1080 Androsterone test system.

862.1085 Angiotensin I and renin test system.

862.1090 Angiotensin converting enzyme (A.C.E.) test system.

862.1095 Ascorbic acid test system.

862.1100 Aspartate amino transferase (AST/SGOT) test system.

862.1110 Bilirubin (total or direct) test system.

862.1113 Bilirubin (total and unbound) in the neonate test system.

862.1115 Urinary bilirubin and its conjugates (nonquantitative) test system.

862.1117 B-type natriuretic peptide test system.

862.1118 Biotinidase test system.

862.1120 Blood gases (PCO_2PO_2) and blood pH test system.

862.1130 Blood volume test system.

862.1135 C-peptides of proinsulin test system.

862.1140 Calcitonin test system.

862.1145 Calcium test system.

862.1150 Calibrator.

862.1155 Human chorionic gonadotropin (HCG) test system.

862.1160 Bicarbonate/carbon dioxide test system.

862.1165 Catecholamines (total) test system.

862.1170 Chloride test system.

862.1175 Cholesterol (total) test system.

862.1177 Cholylglycine test system.

862.1180 Chymotrypsin test system.

862.1185 Compound S (11-deoxycortisol) test system.

862.1187 Conjugated sulfolithocholic acid (SLCG) test system.

862.1190 Copper test system.

862.1195 Corticoids test system.

862.1200 Corticosterone test system.

862.1205 Cortisol (hydrocortisone and hydroxycorticosterone) test system.

862.1210 Creatine test system.

862.1215 Creatine phosphokinase/creatinine kinase or isoenzymes test system.

862.1225 Creatinine test system.

862.1230 Cyclic AMP test system.

862.1235 Cyclosporine test system.

862.1240 Cystine test system.

862.1245 Dehydroepiandrosterone (free and sulfate) test system.

862.1250 Desoxycorticosterone test system.

862.1255 2,3-Diphosphoglyceric acid test system.

862.1260 Estradiol test system.

862.1265 Estriol test system.

862.1270 Estrogens (total, in pregnancy) test system.

862.1275 Estrogens (total, nonpregnancy) test system.

862.1280 Estrone test system.

862.1285 Etiocholanolone test system.

862.1290 Fatty acids test system.

862.1295 Folic acid test system.

862.1300 Follicle-stimulating hormone test system.

862.1305 Formiminoglutamic acid (FIGLU) test system.

862.1310 Galactose test system.

862.1315 Galactose-1-phosphate uridylyl transferase test system.

862.1320 Gastric acidity test system.

862.1325 Gastrin test system.

862.1330 Globulin test system.

862.1335 Glucagon test system.

862.1340 Urinary glucose (nonquantitative) test system.

862.1345 Glucose test system.

862.1360 Gamma-glutamyl transpeptidase and isoenzymes test system.

862.1365 Glutathione test system.

862.1370 Human growth hormone test system.

862.1375 Histidine test system.

862.1377 Urinary homocystine (nonquantitative) test system.

862.1380 Hydroxybutyric dehydrogenase test system.

862.1385 17-Hydroxycorticosteroids (17-ketogenic steroids) test system.

862.1390 5-Hydroxyindole acetic acid/serotonin test system.

862.1395 17-Hydroxyprogesterone test system.

862.1400 Hydroxyproline test system.

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862.1405 Immunoreactive insulin test system.
862.1410 Iron (non-heme) test system.
862.1415 Iron-binding capacity test system.
862.1420 Isocitric dehydrogenase test system.
862.1430 17-Ketosteroids test system.
862.1435 Ketones (nonquantitative) test system.
862.1440 Lactate dehydrogenase test system.
862.1445 Lactate dehydrogenase isoenzymes test system.
862.1450 Lactic acid test system.
862.1455 Lecithin/sphingomyelin ratio in amniotic fluid test system.
862.1460 Leucine aminopeptidase test system.
862.1465 Lipase test system.
862.1470 Lipid (total) test system.
862.1475 Lipoprotein test system.
862.1485 Luteinizing hormone test system.
862.1490 Lysozyme (muramidase) test system.
862.1495 Magnesium test system.
862.1500 Malic dehydrogenase test system.
862.1505 Mucopolysaccharides (nonquantitative) test system.
862.1509 Methylmalonic acid (nonquantitative) test system.
862.1510 Nitrite (nonquantitative) test system.
862.1515 Nitrogen (amino-nitrogen) test system.
862.1520 5'-Nucleotidase test system.
862.1530 Plasma oncometry test system.
862.1535 Ornithine carbamyl transferase test system.
862.1540 Osmolality test system.
862.1542 Oxalate test system.
862.1545 Parathyroid hormone test system.
862.1550 Urinary pH (nonquantitative) test system.
862.1555 Phenylalanine test system.
862.1560 Urinary phenylketones (nonquantitative) test system.
862.1565 6-Phosphogluconate dehydrogenase test system.
862.1570 Phosphohexose isomerase test system.
862.1575 Phospholipid test system.
862.1580 Phosphorus (inorganic) test system.
862.1585 Human placental lactogen test system.
862.1590 Porphobilinogen test system.
862.1595 Porphyrins test system.
862.1600 Potassium test system.
862.1605 Pregnanediol test system.
862.1610 Pregnanetriol test system.
862.1615 Pregnenolone test system.
862.1620 Progesterone test system.
862.1625 Prolactin (lactogen) test system.
862.1630 Protein (fractionation) test system.
862.1635 Total protein test system.
862.1640 Protein-bound iodine test system.
862.1645 Urinary protein or albumin (nonquantitative) test system.
862.1650 Pyruvate kinase test system.

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862.1655 Pyruvic acid test system.
862.1660 Quality control material (assayed and unassayed).
862.1665 Sodium test system.
862.1670 Sorbitol dehydrogenase test system.
862.1675 Blood specimen collection device.
862.1678 Tacrolimus test system.
862.1680 Testosterone test system.
862.1685 Thyroxine-binding globulin test system.
862.1690 Thyroid-stimulating hormone test system.
862.1695 Free thyroxine test system.
862.1700 Total thyroxine test system.
862.1705 Triglyceride test system.
862.1710 Total triiodothyronine test system.
862.1715 Triiodothyronine uptake test system.
862.1720 Triose phosphate isomerase test system.
862.1725 Trypsin test system.
862.1730 Free tyrosine test system.
862.1770 Urea nitrogen test system.
862.1775 Uric acid test system.
862.1780 Urinary calculi (stones) test system.
862.1785 Urinary urobilinogen (nonquantitative) test system.
862.1790 Uroporphyrin test system.
862.1795 Vanilmandelic acid test system.
862.1805 Vitamin A test system.
862.1810 Vitamin B₁₂ test system.
862.1815 Vitamin E test system.
862.1820 Xylose test system.
862.1825 Vitamin D test system.

Subpart C—Clinical Laboratory Instruments

862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.
862.2100 Calculator/data processing module for clinical use.
862.2140 Centrifugal chemistry analyzer for clinical use.
862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.
862.2160 Discrete photometric chemistry analyzer for clinical use.
862.2170 Micro chemistry analyzer for clinical use.
862.2230 Chromatographic separation material for clinical use.
862.2250 Gas liquid chromatography system for clinical use.
862.2260 High pressure liquid chromatography system for clinical use.
862.2270 Thin-layer chromatography system for clinical use.
862.2300 Colorimeter, photometer, or spectrophotometer for clinical use.
862.2310 Clinical sample concentrator.
862.2320 Beta or gamma counter for clinical use.

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862.2400 Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use.
862.2485 Electrophoresis apparatus for clinical use.
862.2500 Enzyme analyzer for clinical use.
862.2540 Flame emission photometer for clinical use.
862.2560 Fluorometer for clinical use.
862.2570 Instrumentation for clinical multiplex test systems.
862.2680 Microtitrator for clinical use.
862.2700 Nephelometer for clinical use.
862.2720 Plasma oncometer for clinical use.
862.2730 Osmometer for clinical use.
862.2750 Pipetting and diluting system for clinical use.
862.2800 Refractometer for clinical use.
862.2850 Atomic absorption spectrophotometer for clinical use.
862.2860 Mass spectrometer for clinical use.
862.2900 Automated urinalysis system.
862.2920 Plasma viscometer for clinical use.

Subpart D—Clinical Toxicology Test Systems

862.3030 Acetaminophen test system.
862.3035 Amikacin test system.
862.3040 Alcohol test system.
862.3050 Breath-alcohol test system.
862.3080 Breath nitric oxide test system.
862.3100 Amphetamine test system.
862.3110 Antimony test system.
862.3120 Arsenic test system.
862.3150 Barbiturate test system.
862.3170 Benzodiazepine test system.
862.3200 Clinical toxicology calibrator.
862.3220 Carbon monoxide test system.
862.3240 Cholinesterase test system.
862.3250 Cocaine and cocaine metabolite test system.
862.3270 Codeine test system.
862.3280 Clinical toxicology control material.
862.3300 Digitoxin test system.
862.3320 Digoxin test system.
862.3350 Diphenylhydantoin test system.
862.3360 Drug metabolizing enzyme genotyping system.
862.3380 Ethosuximide test system.
862.3450 Gentamicin test system.
862.3520 Kanamycin test system.
862.3550 Lead test system.
862.3555 Lidocaine test system.
862.3560 Lithium test system.
862.3580 Lysergic acid diethylamide (LSD) test system.
862.3600 Mercury test system.
862.3610 Methamphetamine test system.
862.3620 Methadone test system.
862.3630 Methaqualone test system.
862.3640 Morphine test system.
862.3645 Neuroleptic drugs radioreceptor assay test system.
862.3650 Opiate test system.
862.3660 Phenobarbital test system.

862.3670 Phenothiazine test system.
862.3680 Primidone test system.
862.3700 Propoxyphene test system.
862.3750 Quinine test system.
862.3830 Salicylate test system.
862.3840 Sirolimus test system.
862.3850 Sulfonamide test system.
862.3870 Cannabinoid test system.
862.3880 Theophylline test system.
862.3900 Tobramycin test system.
862.3910 Tricyclic antidepressant drugs test system.
862.3950 Vancomycin test system.

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SOURCE: 52 FR 16122, May 1, 1987, unless otherwise noted.

Subpart A—General Provisions**§ 862.1 Scope.**

(a) This part sets forth the classification of clinical chemistry and clinical toxicology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required in § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(d) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 16122, May 1, 1987, as amended at 67 FR 58329, Sept. 16, 2002]

§ 862.2 Regulation of calibrators.

Many devices classified in this part are intended to be used with a calibrator. A calibrator has a reference value assigned to it which serves as the basis by which test results of patients are derived or calculated. The calibrator for a device may be (a) manufactured and distributed separately from the device with which it is intended to